the Commissioner announces the order by notice published in the FEDERAL REGISTER.

PART 861—PROCEDURES FOR PERFORMANCE STANDARDS DEVELOPMENT

Subpart A—General

Subpart B—Procedures for Performance Standards Development and Publication

AUTHORITY: 21 U.S.C. 351, 352, 360c, 360d, 360gg–360ss, 371, 374; 42 U.S.C. 262, 264.

SOURCE: 45 FR 7484, Feb. 1, 1980, unless otherwise noted.

Subpart A—General

§ 861.1 Purpose and scope.

(a) This part implements section 514 of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the establishment, amendment, and revocation of performance standards applicable to devices intended for human use.

(b) The Food and Drug Administration may determine that a performance standard, as described under special controls for class II devices in § 860.7(b) of this chapter, is necessary to provide reasonable assurance of the safety and effectiveness of the device. Performance standards may be established for:

(1) A class II device;

(2) A class III device which, upon the effective date of the standard, is reclassified into class II; and

(3) A class III device, as a condition to premarket approval under section 515 of the act, to reduce or eliminate a risk or risks associated with such device.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

[45 FR 7484, Feb. 1, 1980, as amended at 45 FR 23686, Apr. 8, 1980; 57 FR 58404, Dec. 10, 1992]

§ 861.5 Statement of policy.

In carrying out its duties under this section, the Food and Drug Administration will, to the maximum extent practical:

(a) Use personnel, facilities, and other technical support available in other Federal agencies;

(b) Consult with other Federal agencies concerned with standard setting and other nationally or internationally recognized standard-setting entities; and

(c) Invite participation, through conferences, workshops, or other means, by representatives of scientific, professional, industry, or consumer organizations who can make a significant contribution.

§ 861.7 Contents of standards.

Any performance standard established under this part will include such provisions as the Food and Drug Administration determines are necessary to provide reasonable assurance of the safety and effectiveness of the device or devices for which it is established. Where necessary to provide such assurance, a standard will address (but need not be limited to):

(a) Performance characteristics of the device;

(b) The design, construction, components, ingredients, and properties of the device, and its compatibility with power systems and connections to such systems;

(c) The manufacturing processes and quality control procedures applicable to the device;

(d) Testing of the device on either a sample or a 100-percent basis by the manufacturer, or, if it is determined that no other more practical means are available to the Food and Drug Administration to assure the conformity of the device to the standard, providing for testing by the Food and Drug Administration or a third person to ensure that the device conforms to the standard;